Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs
Axsome Therapeutics, Inc. and
Antecip Bioventures II LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AXSOME THERAPEUTICS, INC. and ANTECIP BIOVENTURES II LLC, **Plaintiffs,** **v.** **TEVA PHARMACEUTICALS, INC.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Axsome Therapeutics, Inc. ("Axsome") and Antecip Bioventures II LLC ("Antecip" and, collectively with Axsome, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendant Teva Pharmaceuticals, Inc. ("Teva" or "Defendant"), allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from the Defendant's filing of its Abbreviated New Drug Application ("ANDA") No. 218147 ("Teva's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of

Plaintiffs' dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets prior to the expiration of United States Patent Nos. 10,780,064 ("the '064 patent"), 10,925,842 ("the '842 patent"), 10,940,124 ("the '124 patent"), and 10,966,942 ("the '942 patent") (collectively, "the patents-in-suit"), all owned by Antecip and exclusively licensed to Axsome.

The Parties

2. Axsome is a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics for central nervous system ("CNS") conditions that have limited treatment options.

3. Axsome is a corporation existing under the laws of Delaware, having a principal place of business at 22 Cortland Street, 16th Floor, New York, NY 10007.

4. Antecip is a limited liability corporation existing under the laws of Delaware, having a principal place of business at 630 Fifth Avenue, Suite 200, New York, NY 10111.

5. On information and belief, Teva is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

The Patents-in-Suit

6. On September 22, 2020, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '064 patent, entitled, "Bupropion as a Modulator of Drug Activity." The face of the '064 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the '064 patent; the assignment is recorded with the USPTO at Reel: 052900, Frame: 0032. Axsome is the exclusive licensee of the '064 patent. A copy of the '064 patent is attached hereto as Exhibit A.

7. On February 23, 2021, the USPTO duly and lawfully issued the '842 patent, entitled, "Bupropion as a Modulator of Drug Activity." The face of the '842 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the '842 patent; the assignment is recorded with the USPTO at Reel: 054078, Frame: 0416. Axsome is the exclusive licensee of the '842 patent. A copy of the '842 patent is attached hereto as Exhibit B.

8. On March 9, 2021, the USPTO duly and lawfully issued the '124 patent, entitled, "Bupropion as a Modulator of Drug Activity." The face of the '124 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the '124 patent; the assignment is recorded with the USPTO at Reel: 054078, Frame: 0416. Axsome is the exclusive licensee of the '124 patent. A copy of the '124 patent is attached hereto as Exhibit C.

9. On April 6, 2021, the USPTO duly and lawfully issued the '942 patent, entitled, "Bupropion as a Modulator of Drug Activity." The face of the '942 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the '942 patent; the assignment is recorded with the USPTO at Reel: 054078, Frame: 0416. Axsome is the exclusive licensee of the '942 patent. A copy of the '942 patent is attached hereto as Exhibit D.

The Auvelity® Drug Product

10. Axsome holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets ("NDA No. 215430"), which is sold under the trade name Auvelity®. Auvelity® is a combination of dextromethorphan, an uncompetitive *N*-methyl *D*-aspartate ("NMDA") receptor antagonist and sigma-1 receptor agonist, and bupropion, an aminoketone and CYP450 2D6 inhibitor, approved in adult patients for the treatment of major depressive disorder ("MDD"). The claims of the patents-in-suit cover, *inter alia*, methods of using Auvelity® to treat MDD.

11. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Auvelity®.

Jurisdiction and Venue

12. This Court has jurisdiction over the subject matter of Counts I through IV against Teva pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. As set forth in Paragraphs 14-18 below, the Court has personal jurisdiction over Teva by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

14. On information and belief, Teva purposefully has conducted and continues to conduct business in this Judicial District.

15. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

16. On information and belief, this Judicial District will be a destination for the generic version of Plaintiffs' dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets for which Teva seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218147 ("Teva's Proposed Product").

17. On information and belief, Teva maintains a physical place of business in this Judicial District, in at least Parsippany, New Jersey. Teva's website states that its "US Headquarters" is located in Parsippany, New Jersey. *See* https://www.tevausa.com/contact-us/ (last visited, Mar. 24, 2023). In recent court filings, Teva has admitted that it has a "a principal place of business" in Parsippany, New Jersey. *See, e.g.*, *Neurocrine Biosci., Inc. v. Teva Pharm., Inc., et. al.*, No. 22-cv-965, ECF No. 14 at ¶ 12 (D. Del. Nov. 1, 2022).

18. On information and belief, Teva is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134.

19. For at least the foregoing reasons set forth above in Paragraphs 14-18 above, venue is proper in this Judicial District with respect to Teva pursuant to 28 U.S.C. § 1400(b).

Acts Giving Rise To Counts I-IV

20. Pursuant to Section 505 of the FFDCA, Teva filed ANDA No. 218147 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Teva's Proposed Product, before the patents-in-suit expire.

21. No earlier than February 9, 2023, Teva sent written notice of a Paragraph IV Certification ("Teva's Notice Letter") to Axsome. According to Teva's Notice Letter, Teva filed an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Auvelity®.

22. Teva's Notice Letter alleges that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.

23. On information and belief, in connection with the filing of its ANDA as described above, Teva provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Teva's Paragraph IV Certification"), alleging that the claims of the '064 patent, '842 patent, '124 patent, and '942 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.

24. On information and belief, following FDA approval of Teva's ANDA, unless enjoined by the Court, Teva will make, use, offer to sell, or sell Teva's Proposed Product throughout the United States, or import such a generic product into the United States.

Count I: Infringement of the '064 Patent by Teva

25. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

26. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '064 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

27. A justiciable controversy exists between the parties hereto as to the infringement of the '064 patent.

28. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '064 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

29. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '064 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '064 patent and knowledge that its acts are encouraging infringement.

30. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '064 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's

Proposed Product is designed for a use that infringes one or more claims of the '064 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

31. Failure to enjoin Teva's infringement of the '064 patent will substantially and irreparably damage Plaintiffs.

32. Plaintiffs do not have an adequate remedy at law.

Count II: Infringement of the '842 Patent by Teva

33. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

34. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '842 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

35. A justiciable controversy exists between the parties hereto as to the infringement of the '842 patent.

36. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '842 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

37. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '842 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's

ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '842 patent and knowledge that its acts are encouraging infringement.

38. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '842 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '842 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

39. Failure to enjoin Teva's infringement of the '842 patent will substantially and irreparably damage Plaintiffs.

40. Plaintiffs do not have an adequate remedy at law.

Count III: Infringement of the '124 Patent by Teva

41. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

42. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '124 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

43. A justiciable controversy exists between the parties hereto as to the infringement of the '124 patent.

44. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '124 patent under 35 U.S.C. § 271(a), including at least claim

1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

45. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '124 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '124 patent and knowledge that its acts are encouraging infringement.

46. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '124 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '124 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

47. Failure to enjoin Teva's infringement of the '124 patent will substantially and irreparably damage Plaintiffs.

48. Plaintiffs do not have an adequate remedy at law.

Count IV: Infringement of the '942 Patent by Teva

49. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

50. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the

expiration of the '942 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

51. A justiciable controversy exists between the parties hereto as to the infringement of the '942 patent.

52. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '942 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

53. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '942 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '942 patent and knowledge that its acts are encouraging infringement.

54. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '942 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '942 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

55. Failure to enjoin Teva's infringement of the '942 patent will substantially and irreparably damage Plaintiffs.

56. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment that Teva infringed one or more claims of each of the patents-in-suit by submitting ANDA No. 218147;

(B) A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing Teva's Proposed Product will infringe one or more claims of each of the patents-in-suit ;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 218147 be a date no earlier than the later of the expiration of each of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Teva's Proposed Product until after the expiration of each of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from practicing any method claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of each such patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Teva's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of each of the patents-in-suit;

(G) To the extent that Teva has committed any acts with respect to the methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

(H) If Teva engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Teva's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) A Judgment declaring that each of the patents-in-suit remains valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees, costs, and expenses incurred in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: March 24, 2023

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs
Axsome Therapeutics, Inc. and
Antecip Bioventures II LLC

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Daniel C. Wiesner
Geoffrey A. Kirsner
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy is not related to any other matter currently pending in this Judicial District.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: March 24, 2023

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs Axsome Therapeutics, Inc. and Antecip Bioventures II LLC

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Daniel C. Wiesner
Geoffrey A. Kirsner
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000